

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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U.S. DISTRICT COURT
DISTRICT OF MASS

SERONO, INC.,

Plaintiff,

vs.

FERRING PHARMACEUTICALS, INC.,

Defendant.

Civil Action No. 02-11832 MLW

**FERRING PHARMACEUTICALS, INC.'S
REBUTTAL BRIEF ON CLAIM CONSTRUCTION**

I. INTRODUCTION

Serono's Opening Brief on Claim Construction seems to agree with most of Ferring's proposed claim construction. The only serious disputes apparently relate to the claims that address infertility treatment in the absence of the LH hormone. The parties also seem to agree that the Court should construe the claims based on the time frame of 1984, which is the filing year for both patents in suit.

Serono concedes that the infertility-treatment field was nascent in 1984. To use Serono's words, the year 1984 was "a time when these fertility techniques were still being pioneered." (Brief, p. 1).¹ This is an important concession by Serono, since it means that there was no established language or jargon used by those of skill in the art. Ferring will elaborate below on why this concession is important. Suffice it to say here that, if there is no special technical meaning given to a claim term, then that term should have its ordinary meaning.

¹ References to "Brief" will be to the Serono Opening Brief on Claim Construction dated December 19, 2003.

Serono concedes another, perhaps more crucial point. Serono's Exhibit 13 is Ventruoli (1983), published by Serono itself in 1982, and it shows that Serono has known for more than twenty years that those skilled in the art would have had ample reason to adopt Ferring's claim construction that "FSH alone" means "absolutely no LH." As shown in Exhibit 13, Serono has long been aware that pure FSH is FSH "where all the LH is removed."

In the next section, Ferring will discuss the areas of disagreement between the parties. All of the disputed terms relate to infertility treatment using the FSH hormone alone, in the absence of the LH hormone. Ferring will conclude in Section III with a discussion of the agreed terms between the parties.

II. THE RECITED USE OF FSH ALONE OR IN THE ABSENCE OF LH MEANS THAT NO LH CAN BE PRESENT

In relation to gonadotropins, the essence of the invention claimed in both U.S. patents No. 4,845,077 ("077") and No. 4,589,402 ("402") is indisputably the use of only one hormone, FSH. The prior art employed two hormones, FSH and LH, to treat patients for infertility. Staheli Decl., Exhs. G and C; '402 File History, Paper 3, Amendment Under Rule 115; '077 File History, Paper 7, Response to Final Rejection. In contrast, the patent claims underscore the one-hormone therapy, by using the term "FSH alone" ('402, claim 1). Indeed, certain claims underscore this point by stressing that there must not be any of the LH hormone present. These claims use the phrases "in the absence of exogenous LH" ('077, claims 1 and 8) or "without the presence of exogenous LH" ('402, claim 1).

Based on such explicit language, it is remarkable that Serono argues now that the claim terms in question mean that some LH can be present. Serono attempts to rationalize this

strained interpretation through use of extrinsic literature; that is, evidence largely not found in either patent.² Ferring will point out below why Serono's interpretation should be rejected.

A. Serono Has Offered Multiple Constructions For The "FSH Alone" Claim Terms

Serono itself is confused over the meaning of the claim terms in issue. Serono has proposed at least three interpretations for disputed language related to "FSH alone . . . without the presence of exogenous LH" ('402, claim 1) and "FSH . . . in the absence of exogenous LH" ('077, claims 1 and 8).

Serono's first interpretation appeared on Serono's Claim Chart, served in compliance with the Court's Scheduling Order on December 1, 2003. There Serono proposed that this language should be taken to mean "[g]onadotropins originating outside the patient's body with no detectable traces of LH by 1984 standards. 'In the absence of exogenous LH' means that standard technology circa 1984 was unable to detect the presence of LH in the exogenous gonadotropin."

Serono's second interpretation appeared on December 17th, two days before the Court deadline for opening Markman briefs, in an "Amended Claim Chart." In the latter, Serono significantly changed its proposed interpretation to "[g]onadotropins originating outside the patient's body with no detectable traces of LH by 1984 bioassay technology. 'In the absence of exogenous LH' means that bioassay technology circa 1984 was unable to detect the presence of LH in the exogenous gonadotropin. See, e.g., Kenigsberg et al., *Fertil & Steril.*, Vol. 42, No. 1, p 116-126 (1984)" (new language underscored).

² To avoid confusion and conserve space in this brief, Ferring cites to Serono's scientific literature by lead author name, year of publication, and the Serono exhibit number only. Taking Serono's Exhibit 13 as an example, the scientific paper cited is Venturoli *et al.*, *Induction of ovulation with "pure" human urinary FSH in patients with chronic anovulation and polycystic ovaries*, Serono Symposium, 439-49 (1982). In this brief, Ferring cites that paper simply as "Venturoli (1982) (Serono Exhibit 13)."

Serono's third interpretation appeared in its opening Markman brief, filed December 19th. Without explanation and without defining any of its new terms, Serono there proposed that the disputed terms mean "a composition that is free of any detectable LH biologic activity based on 1984 technology." (Brief, p. 13; emphasis added to highlight new language).

One of the fundamental problems with Serono's proposed claim construction is its lack of consistency and clarity. Serono's construction rests on the basic assumption that some LH can be present, when the physician treats the patient with the FSH-alone therapy. Yet Serono offers no quantitative measurement to determine how much LH can be present. Moreover, there is no one test to determine whether enough LH is present to be detectable. Serono proposes an *in vivo* bioassay, run on non-human species. (Brief, p. 17). Serono proposes an *in vitro* bioassay (*id.*). Serono proposes, without citation, a construction tied to measuring "LH biological activity", which apparently means measuring LH activity in humans. Another test for LH, proffered by Serono (Brief, p. 16), is drawn from a literature citation that actually does not say LH is undetected; rather, it shows detection of LH by bioassay and RIA tests.³

Serono's invitation that the reader consider all of these tests would result in gross uncertainty to a term, "FSH alone," which needs no clarification. The Court should reject this invitation.

Serono's lack of clarity is evident as well in an erroneous suggestion that one skilled in the art, circa 1984, did not need to be a treating physician. Both of the patents in suit deal with methods used by a medical doctor to treat infertility. Thus, it is a medical doctor who would decide what "FSH alone" means and not, for instance, a researcher, who may use one of many tests to determine whether a compound contains LH. Yet Serono's definition of one

³ Schenken (1983) (Serono Exhibit 14), p. 51.

skilled in the art seems to suggest that a biochemist, a researcher, or a nurse in a fertility clinic may be the relevant skilled person in this context. (Brief, p. 11). In any event, no such nuance is needed to understand the claim terminology in question. No LH means no LH. FSH “alone” means FSH without LH.

Where a patentee proposes a claim construction that is confusing and ambiguous, the term must be narrowly construed, against the patentee. *Rackman v. Microsoft Corp.*, 102 F. Supp. 2d 113, 122 (E.D.N.Y. 2000). Furthermore, while it is always difficult to sight on multiple moving targets, Ferring believes that Serono’s evidence in support of any of these proposed constructions not only is confusing, but also is extrinsic to the patent record. As noted in Ferring’s opening brief, extrinsic evidence is disfavored in claim construction. Ferring will discuss below the reasons why Serono’s extrinsic evidence should be rejected.

B. Serono Confuses What Should Be A Simple Claim Construction By Relying On Extrinsic Evidence

Serono relies on a bevy of terms that are not in the claims. Indeed, nowhere do the patents or the prosecution histories refer to terms, such as “bioassays,” “bioactivity,” “bioassay technology,” “detectable LH bioactivity,” and the “detectability” of exogenous LH. Serono uses all these terms without definition.

To argue for its multiple claim constructions, Serono invoked seven scientific publications and one quotation from the U.S. Pharmacopeia XX. (Serono Exhibits 6, 7, 12, 13, 14, 15, 17, and 18). None of these documents is mentioned in the ‘077 specification. Only one, Schenken (1984) (Serono Exhibit 7), appears in the file history to ‘077 as an inch-high “abstract,” which itself does not mention “bioassays,” “bioactivity,” “bioassay technology,” “detectable LH bioactivity,” and the “detectability” of LH in gonadotropins. Only three of the documents in question can be found in the ‘402 patent specification – Schenken (1984) (Serono

C. **Serono's Proposed Claim Construction, Relying On Selective Extrinsic Evidence, Would Complicate And Not Clarify Meaning And Would Broaden The Claims Impermissibly**

Serono proffers its extrinsic evidence to support some or all of its different claim constructions, based on some understanding of the claim terms by those skilled in the art. (Brief, pp. 13-14). Serono argues that there is an accustomed and special meaning to using the FSH hormone alone. But there is no reason to think that was true in 1984. Claim construction does not begin with an inference of a special meaning. Claim construction begins with the words of the claim.

“[T]he claim construction inquiry . . . begins and ends in all cases with the actual words of the claim.” *Biogen*, 113 F. Supp. 2d at 95-96 (citation omitted). Where a claim “does not appear to convey any special technical meanings” its terms will be given their plain and ordinary English meaning. *Middleton, Inc. v. Minnesota Mining & Mfg. Co.*, 311 F.3d 1384, 1387 (Fed. Cir. 2002).

Serono has not shown that the words of the claim here mandate a search for “special technical meanings.” On the contrary, Serono’s characterization of the state of the art suggests such a showing cannot be made. Serono describes a “pioneering” time when the development of specialized jargon would be unlikely: “Both patents date back to 1984, a time when these fertility techniques were still being pioneered.” (Brief, p. 1). “Dr. Hodgen and his co-inventors were the first to develop infertility treatment regimens using ‘pure’ FSH.” (*Id.* at 2). “At the time of the inventions, the complex roles of FSH and LH in the development of follicles and maturation of eggs resulting in ovulation were still being determined.” (*Id.* at 4). Importantly, as to the understanding of the FSH-related claim terms, Serono also says that at the time of the inventions, the use of “FSH alone” to treat infertility was not known, and that

physicians were instead using “a mixture of FSH and LH” as their drug of choice. (*Id.* at 6; ‘402 File History, Paper 3, p. 2). In this early period, therefore, those skilled in the field would have been unlikely to superimpose particular jargon or a special meaning over the inventors’ plain English. The inventors employed simple, direct words in their claims, such as “alone,” “absence,” and “without.” The Court should not use extrinsic evidence to confuse these straightforward terms.

More importantly, Serono cannot rely on evidence outside the specifications and on prosecution histories impermissibly to broaden its claims beyond what they say in plain and ordinary English. The contested terms -- “FSH alone . . . without the presence of exogenous LH” and “FSH . . . in the absence of exogenous LH” -- are limitations. By vague references to the state of the pertinent art in 1984, Serono’s multiple and confusing constructions convey the notion that the claims at bar should be read to permit some amount of LH. To so read “FSH alone,” however, would effectively read out of the claims a clear limitation, expressed in plain and ordinary English. Where there is no indication that a patentee used claim language in a special or unusual manner, the language selected by the patentee must be given its ordinary meaning. *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 93 F.3d 1572, 1583 (Fed. Cir. 1996) (the patentee chose the language and “it must live with the language it chose”); *Rackman v. Microsoft Corp.*, 102 F. Supp. 2d 113, 121 (E.D.N.Y. 2000) (“insertable storage medium” could not mean “any storage medium”); *Biogen*, 113 F. Supp. 2d at 96 (words of the claim must have “a textual reference” justifying a change in the scope of the claims based on the specification).

In fact, the applicable rules point the other way. To the extent that a patentee’s broad reading of a claim term would be ambiguous, the term should be construed narrowly and

against the patentee. *Rackman*, at 122. Based on its multiple claim interpretations and the extrinsic evidence Serono relies upon, therefore, Serono's attempt to broaden the claims should be rejected.

D. Serono's Extrinsic Evidence, Even If It Were Considered, Supports Ferring's Claim Construction

Serono argues that one of its products was Metrodin, a "preferred embodiment" of the '402 patent. (Brief, pp. 7, 13-16). Of course, Metrodin is not mentioned in either patent; nor was Metrodin commercially available in 1984, since it received FDA clearance in 1986. Nevertheless, Serono invokes this extrinsic evidence to argue that those of skilled in the art understood, in 1984, that the FSH-alone claim terms referred to Metrodin.

A principled reading of the proffered extrinsic evidence actually contravenes Serono's position, however, and directly supports Ferring's claim construction. These publications also show that the claims, per Ferring's construction, would read on Serono's alleged preferred embodiment.

1. Serono's extrinsic evidence proves that the claims, in accordance with Ferring's construction, read on Serono's alleged preferred embodiment

Serono's own extrinsic evidence actually shows that both of "pure FSH" and "Metrodin" denote FSH only. That is, the evidence relates the use of a single gonadotropin, with all of the LH removed.

Serono characterizes its extrinsic evidence as "published articles contemporaneous to the patent and well known to persons in the art at the time." (Brief, p. 15). Among those papers is Venturoli (1982) (Serono Exhibit 13). In Venturoli (1982), "pure FSH" is defined: "The pure FSH is extracted from HMG by separating the two hormones (FSH-LH),

first by chromatography and then by immunochromatography, **where all the LH is removed.**” *Id.* at 440 (emphasis added).

Importantly, Venturoli’s statement applies to Metrodin as well. Another of Serono’s published articles is Venturoli (1983), which indicates that those skilled in the art thought that Metrodin was “pure human FSH.” From its title and text, Venturoli (1983) (Serono Exhibit 12) makes plain that Dr. Venturoli was reporting his work with Metrodin, the use of which, according to Serono, is a preferred embodiment to the ‘402 patent. (Brief, pp. 13-14). On page 30, Dr. Venturoli states that “in this experiment we used urofollitrophin (Metrodin)” from Serono. He expressly identifies Metrodin as “pure FSH” by noting that Metrodin contains “75 I.U. of **pure human FSH** by urinary extraction.” *Id.*

Serono maintains that Ferring’s claim construction would fail because, thus read, the claims would not read on the “preferred embodiment,” Metrodin. (Brief, p. 14). Serono also argues, and therefore concedes for purposes of Ferring’s analysis here, that “persons in the art at the time [the patents were applied for] equated the terms pure FSH, “FSH alone,” and Metrodin. (Brief, p. 16).

Ferring does not concede that either patent articulates a preferred embodiment. Ferring repeats that Serono has made no showing that its extrinsic evidence was incorporated by reference in a way that would reflect on or disclose an embodiment of the claimed invention.

Nevertheless, if these extrinsic pieces of evidence are of any relevance, Dr. Venturoli’s published articles support the notion that, in 1984, a person skilled in the art would conclude that Metrodin was pure FSH. Certainly, Dr. Venturoli’s work suggests to his readers that Metrodin was totally free of LH. This is consistent with Ferring’s claim construction, which is that there be “absolutely no LH” in the patient’s treatment. Thus, if Metrodin is the preferred

embodiment, there is nothing to suggest that Ferring's claim construction, of no LH, does not read on it.

Serono's admission that Dr. Venturoli's papers are "published articles contemporaneous to the patent and well known to persons in the art at the time" is important. Even if it could be shown that Dr. Venturoli's published statements were dead wrong about pure FSH having all the LH removed, Serono concedes that those of skill in the art believed his papers and shared his views. Thus, even if Venturoli's papers are wrong, they are evidence that Ferring's claim interpretation is correct. Venturoli supports Ferring's position that the plain and ordinary English words of the claims mean – and would be understood by those of skill in the art in 1984 to mean – just what they say. "FSH alone" and the other terms mean simply "no LH."

In short, Serono's own evidence supports Ferring's position that the contested terms mean "only FSH, the FSH being the only gonadotropin so administered; and there being absolutely no LH administered with the FSH." *See* Appendix A to Ferring's opening brief.

2. Serono published the Venturoli evidence, supporting Ferring's claim construction, more than twenty years ago; hence, Serono should be estopped from relying on inconsistent extrinsic evidence

In light of the Venturoli papers, Serono's reliance on the other cited extrinsic evidence is confusing, at best. Serono itself published the Venturoli (1982) paper, equating "pure FSH" with "no LH." Since 1982, therefore, Serono knew that scientists like Dr. Venturoli equated "pure" FSH with gonadotropins "where all the LH is removed." Since 1982 Serono knew, along with others skilled in the art, that scientists like Dr. Venturoli also equated "pure" FSH with Metrodin. Thus, since 1982 Serono has known that those skilled in the art would have reason to believe that Metrodin had "all the LH removed," and that Metrodin has "no LH."

In this lawsuit, Serono now relies on other extrinsic evidence – Kenigsberg (1984) (Serono Exhibit 6) – to say that, because the LH was undetectable in Metrodin in a single study, the claims at issue should have a construction that broadens “FSH alone” to mean “some LH.” Despite Venturoli’s two papers, on which Serono itself relies, Serono thus wants a reading of the claim terms that includes products *containing* LH. (Brief, pp. 7, 13-14, and 16).

Given its longstanding knowledge, Serono’s argument is, if not disingenuous, at the least very confusing.⁵ This evidence does nothing to clarify the terms at issue. It should be rejected.

E. Serono’s Extrinsic Evidence Also Should Be Rejected Because It Sheds No Light On The Meaning Of The Terms At Issue

Even if, *arguendo*, Serono’s proffered evidence were deemed probative, its invocation still must fail. As Serono acknowledges, evidence may be marshaled to construe a claim only if it “sheds light” on the meaning of a claim term. *Kumar v. Ovonie Battery Co., Inc.*, 351 F.3d 1364 (Fed. Cir. 2003). (Brief, pp. 14-15). A review of Serono’s “published” and “contemporaneous” articles and its excerpt from the U.S. Pharmacopeia, show that this evidence, taken as a whole, is too confusing to support any proposed claim construction. What follows is a listing of the publications cited by Serono, and Ferring’s interpretation of what aspect of that evidence, if any, “sheds light” on the term “FSH alone”:

- Venturoli *et al.*, (1983) (Serono Exhibit 12). This paper **identifies to those of skill in the art that Metrodin is “pure human FSH.”**

⁵ Serono has failed to justify its resort to extrinsic evidence generally. Serono also has failed to explain its reliance on Dr. Venturoli’s work in particular, and Serono has failed to reconcile Dr. Venturoli’s work with the other extrinsic scientific evidence on which it relies. Ferring respectfully suggests that such extrinsic evidence should be rejected. “Once a dispute over claim construction arises, ‘experts’ should also not be heard to inject a new meaning into terms that is inconsistent with what the inventor set forth in his or her patent and communicated, first to the patent examiner and ultimately to the public.” *Bell & Howell*, 132 F.3d at 706.

- Venturoli *et al.*, Serono Symposium (1982) (Serono Exhibit 13). Those of skill in the art would learn from this study what pure FSH was. This paper, published by Serono itself and known to Serono for 21 years, **describes for those of skill in the art that pure FSH is a gonadotropin from which “all the LH is removed.”**

“The **pure FSH is extracted from HMG** by separating the two hormones (FSH-LH), first by chromatography and then by immunochromatography, where **all the LH is removed.**”

Id. at 440 (emphasis added).

- Schenken *et al.*, (April 1984) (Serono Exhibit 7) uses pure FSH on monkeys. This paper, coauthored by inventor Hodgen, **does not contradict Dr. Venturoli’s statement that this is FSH with “all the LH removed.”**
- Kenigsberg, *et al.*, (1984) (Serono’s Exhibit 6) is Serono’s solitary reference to the “detectability” of LH. In it, the authors use pure FSH identified as Metrodin from Serono. This paper, again coauthored by inventor Hodgen, notes that “using an in vitro bioassay, LH was undetectable” in this preparation. **It does not say undetectable LH is present in Metrodin, nor does it say that undetectable LH is understood to be present in pure FSH. What it does say – LH was undetectable – is consistent with Dr. Venturoli’s characterization that, in Metrodin and pure FSH, “all the LH is removed.”**
- Schenken *et al.*, (1983) (Serono Exhibit 14) uses pure FSH but does not say anything about whether LH is measurable in pure FSH. It reports **two different tests for LH: “RIA and bioassay.”** The authors, including inventor Hodgen, do not discuss “bioactivity of LH” or “detectable LH bioactivity” but **do not contradict Dr. Venturoli’s statement that “pure FSH” is FSH from which “all the LH is removed.”**
- Hodgen G.D., (1982) (Serono Exhibit 15). The inventor describes using pure FSH and identifies that gonadotropin as < 0.1% LH on page 296, but **inventor Hodgen does not contradict Dr. Venturoli’s statement that “pure FSH” is FSH from which “all the LH is removed.”**
- United States Pharmacopeia XX (1980) (Serono Exhibit 18) does not shed light on the claim terms, but **its very existence suggests that a person of skill in the art would understand that LH was measurable by bioassay in gonadotropins.**

Far from shedding light on the meaning “FSH alone,” these articles engender some confusion on this point. The confusion is evident in Serono’s own shifting interpretations. Serono has suggested some or all of the following: LH may be present as long as there are either “no detectable traces of LH by 1984 standards” (Serono’s December 1 definition), or “no detectable traces of LH by 1984 bioassay technology” (Serono’s December 17 definition), or “a

composition that is free of any detectable LH biologic activity based on 1984 technology” (Serono’s definition in its brief at p. 13). This extrinsic evidence should be rejected in favor of the plain meaning of the claim terms.

III. AGREED UPON TERMS

A. The Word “Antagonist” Found In The Claims Should Be Given Its Common Meaning, And It Should Be Made Clear That Antagonist Does Not Include Agonists

The word “antagonist” appears only in the ‘077 patent. It is found in independent claims 1, 8 and 13 at issue. In its opening brief, Ferring argued the importance of distinguishing between the “antagonist” and “agonist.” Ferring asks the Court to make clear “antagonist,” as used in the above-referenced claims, does not include agonists.

Serono seems to concede this point by stating the following: “The ordinary meaning of this limitation [antagonist] is confirmed by the file history, which described a GnRH antagonist as ‘a GnRH analog that binds the GnRH receptor without evoking secretion.’” (Brief, p. 18, emphasis added). In addition, Serono concedes that the invention described in the ‘077 patent relates to an antagonist which bound the receptor site “without evoking secretion of FSH and LH.” (Brief, p. 9).

Clinically and physiologically, agonists work in an entirely different manner from antagonists. As Ferring pointed out in its opening brief, agonists work by occupying a receptor in the pituitary, much like gonadotropin releasing hormone. The agonist then causes an abundance of secretion. The antagonist stops secretions, as Serono concedes. From these facts it is clear that the claims do not include agonists.

B. Daily Administration Of FSH Means Administration Once In Every Twenty-Four Hour Period

Claims 2, 9, and 16 of the '077 patent refer to daily administration or a daily amount of FSH. These terms should be construed to mean administration of FSH once in every twenty-four hour period. Serono did not construe these terms in its first claim construction chart. Nothing in Serono's opening brief suggests that Serono disagrees with this claim construction. The Court should construe this term according to its plain meaning.

C. FSH And LH In Combination Means Conventional Combinations Of FSH and LH

Dependent claim 14(b) of the '077 patent refers to FSH and LH in combination. Ferring argued in its opening brief that this refers to conventional combinations of FSH and LH in 1984, which meant an approximate 1 to 1 ratio of the two hormones. Serono seems to concede that construction by its discussion of the term human menopausal gonadotropin ("HMG"). Serono points out that in 1984, the mixture of gonadotropin hormones, which were purified from the urine of post-menopausal women, were commonly referred to as HMG. (Brief, p. 1). More importantly, Serono concedes that these hormone mixtures "comprised (and still comprise) roughly equal amounts of FSH and LH". (Brief, p. 2). Thus, Serono concedes that the term FSH and LH in combination references the conventional combination used in 1984. That is, approximately, or to put it in Serono's words, "roughly" equal amounts of FSH and LH or a 1 to 1 ratio.

Accordingly, the Court should construe the term found in claim 14(b) of the '077 patent "FSH and LH in combination" to mean conventional combinations of roughly a 1 to 1 ratio.

D. Administration Of An Antagonist Co-Jointly With FSH Means Giving The Patient The Two Drugs On The Same Day

Serono apparently concedes that, in claims 1 and 13 of the '077 patent, the phrase "co-jointly with said FSH" means that the two drugs are administered to the patient at the same time. Ferring favors specifying that this phrase means that the two drugs are given within 24 hours of each other. According to Serono, this means that the administration of the two drugs are "closely timed". (Brief, p. 19). Serono then states that Ferring and Serono essentially agree on the meaning of this term. (Brief, p. 19). Ferring asked the Court specifically to construe the term to mean that the two drugs must be given within 24 hours of each other.

E. Suppressing Estrogen Variability Means Only A Method Of Suppressing Estrogen Production And No Other Purpose Or Effect

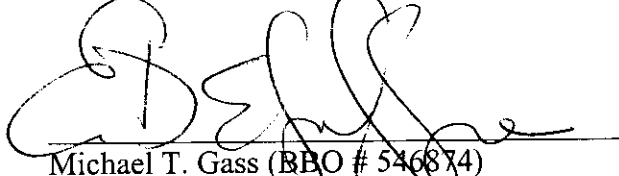
The parties seem to agree on the construction of this term, found in claim 13 of the '077 patent. (Brief, p. 20). It is important that the Court construe this term to mean that the gonadotropin treatment of the patient includes a step of estrogen suppression, using an antagonist. Ferring has asked the Court to specify in its ruling that the method recited in the claim is applied for no effect other than to suppress estrogen levels in the ovary.

IV. CONCLUSION

Ferring submitted Appendix A with its opening brief which proposes a claim construction which is consistent with the plain meaning of the terms found in the patents in suit. Serono's brief asks this Court to consider extrinsic evidence which actually supports Ferring's proffered construction that FSH alone means treating patients by using the FSH hormone alone, without any LH hormone present. The Court should reject Serono's extrinsic evidence and adopt the construction found in Ferring's Appendix A.

Dated this 14 day of January, 2004.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Michael T. Gass", written over a horizontal line.

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